



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service  
Food and Drug Administration

94368d

San Francisco District  
1431 Harbor Bay Parkway  
Alameda, CA 94502-7070  
Telephone: 510/337-6700

VIA CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

Our Reference: FEI 3004107032

October 17, 2003

David S. Cheng, Vice President  
Ting Shun Shin Shipping Agency  
P.O. Box 2849  
Hagatna, Guam 96932

**WARNING LETTER**

Dear Mr. Cheng:

On July 15, 16, and 22, 2003, we inspected your seafood processing facility located at 1026 Cabras Highway, Warehouse 1, Bay 3, Piti, Guam. We found that you have a serious deviation from the Seafood HACCP regulations in Title 21, Code of Federal Regulations, Part 123 (21 CFR 123). In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fish and fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your refrigerated histamine forming fish, e.g., tuna and marlin, are adulterated, in that the fish have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act and the Seafood HACCP regulation through links in FDA's home page at [www.fda.gov](http://www.fda.gov). See attached handout on how you can obtain a copy of the Fish & Fisheries Products Hazards & Controls Guidance, 3<sup>rd</sup> edition, June 2001. We listed the deviation on a Form FDA-483 and discussed them with you at the conclusion of the inspection. Your serious HACCP deviation was:

You must conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur and you must have a written HACCP plan to control any food safety hazards that are likely to occur, to comply with 21 CFR 123.6(a) and (b). However,

your firm does not have a HACCP plan to control histamine formation as a result of time/temperature abuse in histamine forming fish, e.g., tuna and marlin, received directly from the harvest vessel.

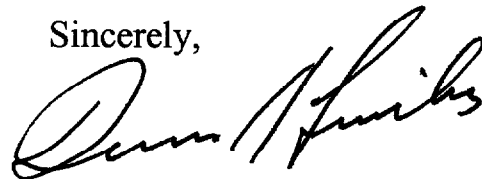
Sufficient time has passed, since our inspection of July 2003 and our presentation of the FDA 483 Inspectional Observations to you, to correct the violations at your facility. If you have not made corrections, you must immediately take appropriate steps to correct the violations. We may initiate regulatory action without further notice if you do not correct these problems. For instance, we may take further action to seize your products and/or enjoin your firm from operating.

Please respond in writing within fifteen (15) working days of receipt of this letter. Your response should outline the specific things you are doing to correct the deviation. You may wish to include in your response documentation such as copies of your HACCP plan, HACCP monitoring records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay, and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the current Good Manufacturing Practices (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your response should be directed to: Ms. Erlinda N. Figueroa, Compliance Officer, U.S. Food and Drug Administration, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070. If you have any questions regarding any issue in this letter, please contact Ms. Figueroa at (510) 337-6795.

Sincerely,

A handwritten signature in black ink, appearing to read "Dennis K. Linsley", written in a cursive style.

Dennis K. Linsley  
District Director  
San Francisco District